

with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of PDP is required*. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any tongs antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a tongs antichoke device that was in commercial distribution before May 28, 1976. Any other tongs antichoke device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[51 FR 40389, Nov. 6, 1986, as amended at 64 FR 18329, Apr. 14, 1999]

§ 874.5550 Powered nasal irrigator.

(a) *Identification*. A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.5800 External nasal splint.

(a) *Identification*. An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 874.5840 Antistammering device.

(a) *Identification*. An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and

that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitant or repetitive speech.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

Subpart A—General Provisions

Sec.

876.1 Scope.

876.3 Effective dates of requirement for premarket approval.

876.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

876.1075 Gastroenterology-urology biopsy instrument.

876.1300 Ingestible telemetric gastrointestinal capsule imaging system.

876.1400 Stomach pH electrode.

876.1500 Endoscope and accessories.

876.1620 Urodynamics measurement system.

876.1725 Gastrointestinal motility monitoring system.

876.1735 Electrogastrography system.

876.1800 Urine flow or volume measuring system.

Subpart C—Monitoring Devices

876.2040 Enuresis alarm.

Subpart D—Prosthetic Devices

876.3350 Penile inflatable implant.

876.3630 Penile rigidity implant.

876.3750 Testicular prosthesis.

Subpart E—Surgical Devices

876.4020 Fiberoptic light ureteral catheter.

876.4270 Colostomy rod.

876.4300 Endoscopic electrosurgical unit and accessories.

876.4370 Gastroenterology-urology evacuator.

876.4400 Hemorrhoidal ligator.

876.4480 Electrohydraulic lithotripter.

876.4500 Mechanical lithotripter.

876.4530 Gastroenterology-urology fiberoptic retractor.

876.4560 Ribdam.